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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/575,961 | 03/23/2007 | Claudia Lange | 12103-9 | 5657 |

757 7590 08/06/2009

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| EXAMINER | |
|---|---|
| LONG, SCOTT | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 08/06/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/575,961 | LANGE ET AL. | |
| | Examiner | Art Unit | |
| | SCOTT LONG | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9,15-18,26,27 and 33-37* is/are pending in the application.

4a) Of the above claim(s) *3-9, 15-18, 26, 27 and 33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/4/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Examiner acknowledges the election, without traverse, of Group I directed to a method for producing blood products, in the reply filed on 2 July 2009. The applicant has also elected the following species, with traverse: myeloid stem cells (blood product species), SCF, FL, IL3, and IL6 (culture conditions comprising a combination of growth factors).

The applicant traverses the species election of blood product. The applicant states "the Examiner has not shown that there is a serious burden on the Examiner." The species of blood products described in the claims encompass myeloid stem cells, endothelial cells, lymphoid stem cells, dendritic cells, erythroid cells, and megakaryocytes. Each of these cells types has a distinct structure which is different from the other. Searching for the culturing conditions required to differentiate the mesenchymal stem cell into one of the species of blood products will not necessarily overlap all blood products claimed. Therefore, each species of method would require different conditions to produce a specific species of blood products. At minimum, these various methods would require different search terms. Therefore a search for each of these species is considered burdensome. Accordingly, the applicant's traversal is unpersuasive.

Further, the applicant traverses the species of culture conditions, stating, "the Examiner has not shown that there is a serious burden on the Examiner's search within

the species of myeloid stem cells for growth factor combinations." The examiner finds this argument unpersuasive, because the sentence has not made a complete logical argument. The examiner cannot understand the applicant's logic found in the phrase, "search within the species of myeloid stem cells for growth factor combinations." The claims are not directed to myeloid cells comprising growth factors. There being nothing to traverse, the applicant's traversal is unpersuasive. Furthermore, the examiner refers the applicant to the examiner's response to the traversal of blood product species, where the examiner indicates a search burden because the different species of methods require different culture conditions and consequently require different search queries.

Therefore, the examiner makes the restriction final.

## *Claim Status*

Claims 1-9, 15-18, 26, 27 and 33-37 are pending. New claim 37 has been added. However, claims 3-8, 9, 15-18, 26, 27 and 33-36 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claim 10-14, 19-25 and 28-32 are cancelled. Claims 1-2 and 37 are under current examination.

### *Oath/Declaration*

The oath or declaration, having the signatures of all inventors, received on 23 March 2007 is in compliance with 37 CFR 1.63.

### *Information Disclosure Statement*

The Information Disclosure Statements (IDS) filed on 11 May 2006 consisting of 3 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

### *Priority*

This application claims benefit as a 371 of PCT/EP04/11570 (filed 14 October 2004) which claims benefit of provisional U.S. Application 60/510,980 (filed 14 October 2003). The instant application has been granted the benefit date, 14 October 2003, from the application 60/510,980.

### *Claim Objections*

Claims 1-37 are objected to because of the following informalities: The last word of claim 1 is “products.” There are some irregularities with the singular/plural agreement within the claim Because many of the dependent claims are directed to producing a single product, all the claims would be in better grammatical form if the word, “products” were changed to “product.”

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Peled et al (US2002/0114789) and as evidenced by Faiqa Sadique (Masters Thesis).

Claim 1 is directed to a method of producing blood products in *vitro,* the method comprising: a) isolating non-SV40 transformed mesenchymal stem cells which are CD34-negative, and which are negative for CD45 and positive for CD105, CD59, CD90, CD13, and MHC I after at least one passage in culture; and b) culturing said isolated non-SV40 transformed mesenchymal stem cells with at least one of the following growth factors added individually or in combinations thereof: stem cell factor (SCF), thrombopoietin (TPO), fit-3 ligand (FL), interleukins, including interleukin-3 (IL-3) and interleukin-6 (IL-6), granulocyte-colony stimulating factor (G-CSF), granulocyte-macrophage colony stimulating factor (GM-CSF), erythropoietin (Epo), vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF), hepatocyte growth factor (HGF), insulin-like growth factor (IGF), epidermal growth factor (EGF), leukaemia inhibitory factor (LIF), and hydrocortisone (HC), for a time sufficient to produce at least one type of blood products. The applicant has elected the species of method for producing myeloid stem cells comprising culturing with SCF, FL, IL3, and IL6. Peled teaches an embodiment in which bone marrow

mesenchymal stems (page 4, parag.0061) are cultured with a variety of cocktails (page 1, parag.0007) including the specific combination of SCF, IL3, IL6, and Flt3 ligand (page 3, parag.0057). into myeloid stem cells. Sadique teaches that bone marrow mesenchymal stem cells inherently are negative for CD34 and CD45 and are positive for CD105, CD59, CD90, CD13, and MHC I (page 11, 1st parag).

Claim 2 is directed to the method of claim 1, wherein said at least one type of blood products comprises myeloid stem cells. Peled teaches that myeloid stem cells are produced by their method of culturing.

Claim 37 is directed to a method of producing blood products in *vitro,* the method comprising: a) isolating non-SV40 transformed mesenchymal stem cells which are CD34-negative, and which are negative for CD45 and positive for CD105, CD59, CD90, CD13, and MHC I after at least one passage in culture; and b) culturing said non-SV40 transformed mesenchymal stem cells which are CD34-negative, and which are negative for CD45 and positive for CD105, CD59, CD90, CD13, and MHC I for at least one additional passage. Peled teaches culturing bone marrow mesenchymal stem cells having the recited markers by standard culturing conditions, including a sufficient number of weeks such that more than one passage would be required.

Accordingly, Peled et al. anticipated the instant claims.

## ***Conclusion***

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/
Patent Examiner, Art Unit 1633